DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 18, 2014

Competitive Engineering, Incorporated
David M. Davis
Engineering Manager
3371 East Hemisphere Loop
Tucson, Arizona 85706

Re: K130019
Trade/Device Name: J-Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 24, 2014
Received: September 30, 2014

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

J-Screw Intended Use:

The J-Screw indicated for use in osteotomy, reconstruction, arthrodesis, joint fusion, fracture repair, and fracture fixation of small bones of the upper and lower extremities.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

6. 510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the J-Screw is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) Summary.

Applicant:	Competitive Engineering, Inc.
Address:	3371 E. Hemisphere Loop
	Tucson, AZ 85706
Contact Person:	David M. Davis
Telephone:	520-746-0270 X-106
Fax:	520-746-0481
Preparation Date:	November 13, 2014
Device Trade Name:	J-Screw
Common Name:	Compression screw
Regulation Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Product Code:	HWC
Regulatory Class;	Class II
Legally Marketed Predicates:	StayFuse (K990804) FlexFusion Fixation implant (K110445) Nextra Ti Hammertoe Correction System (K122031) Arthrex K-Wire (K052736)
Device Description:	The J-Screw is a two part bone screw for use in osteotomy, reconstruction, arthrodesis, joint fusion, fracture repair, and fracture fixation of small bones of the upper and lower extremities. The unique design of the device allows it to fixate or fuse small bones with infinitely adjustable fusing compression, in a fixed yet flexed position.

510(k) Summary of Safety and Effectiveness for the J-Screw continued:

Intended Use:	The J-Screw is indicated for use in osteotomy, reconstruction, arthrodesis, joint fusion, fracture repair, and fracture fixation of small bones of the upper and lower extremities.
Performance Data:	Performance data gathered for insertion and removal torque, torsional yield strength, maximum torque, breaking angle, as well as axial pullout strength was gathered as outlined by ASTM F543-13 with qualified processes and material. Performance data gathered for static cantilever bending force submitted with test outline.
Conclusion:	The J-Screw possesses the same technologic characteristics of the predicate devices. These characteristics include the intended use, basic threaded design, material, size as specified by medical professionals, and fundamental technology. The J-Screw is substantially equivalent to the predicate bone fixation devices.